510(k) Summary
Vitoss Bioactive Foam Bone Graft Substitute

510(k) Number (if known): **K083033**

NOV - 6 2008

Sponsor:	Orthovita, Inc. 45 Great Valley Parkway Malvern, PA 19355 USA (t) 610-640-1775 – (f) 610-640-1714
Company Representative:	Deborah L. Jackson, RAC Regulatory Affairs Specialist (email) djackson@orthovita.com
Date Prepared:	November 4, 2008
Device Trade Name:	Vitoss Bioactive Foam Bone Graft Substitute
Common or Usual Name:	Bone Void Filler
Regulation Number:	888.3045
Regulation Name:	Resorbable calcium salt bone void filler device
Regulatory Class:	Class II
Product Code:	MQV
Predicate Devices:	Vitoss Bioactive Foam Bone Graft Substitute - K072184 Vitoss Bioactive Foam Bone Graft Substitute – STRIP and PACK - K081439
Device Description:	Vitoss Bioactive Foam Bone Graft Substitutes are resorbable, osteoconductive implants with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone.

Intended Use:

Vitoss Bioactive Foam Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Bioactive Foam is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Vitoss Bioactive Foam Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis and spine, which includes posterolateral fusion procedures), and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Performance Data:

Performance testing was conducted to ensure that Vitoss Bioactive Bone Graft Substitutes met the predetermined design specifications. In all instances, Vitoss Bioactive Foam Bone Graft Substitutes functioned as intended.

Vitoss Bioactive Foam Bone Graft Substitutes are osteostimulatory based on in-vitro studies in which calcium phosphate growth was induced on the surface of the Vitoss Bioactive Foam after exposure to simulated body fluid. This phenomenon was not observed in control samples in which there was no bioactive glass component. The osteostimulatory nature of Vitoss Bioactive Foam Bone Graft Substitute has not been correlated to human clinical experience.

Substantial Equivalence:

Information within this submission supports substantial equivalence.

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Date Prepared:	November 4, 2008
Device Trade Name:	Vitoss Foam Bone Graft Substitute
Common or Usual Name:	Bone Void Filler
Regulation Number:	888.3045
Regulation Name:	Resorbable calcium salt bone void filler device
Regulatory Class:	Class II
Product Code:	MQV
Predicate Devices:	Vitoss Scaffold Foam Bone Graft Material – K032288
Device Description:	Vitoss Foam Bone Graft Substitute is a porous calcium phosphate resorbable material combined with Type I bovine collagen for the repair of bony defects. It is an osteoconductive porous implant with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone. Pore diameters in the scaffold range from 1 μm to 1000 μm (1 mm). All implants are provided sterile. Vitoss Foam Bone Graft Substitute guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When Vitoss Foam Bone Graft Substitute is placed in direct contact with viable host bone, new bone grows in apposition to the surfaces of the implant. As the implant resorbs, bone and other connective tissues grow into the space previously occupied by the scaffold.

Intended Use:

Vitoss Foam Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Foam Bone Graft Substitute is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Vitoss Foam Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis and spine, which includes posterolateral fusion procedures), and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Performance Data:

Pre-clinical animal data demonstrate that Vitoss Foam Bone Graft Substitute supports bone growth into a metaphyseal defect. These data show that Vitoss Foam Bone Graft Substitute is resorbed concurrently with bone ingrowth and remodeling. These results, in conjunction with in-vitro data, demonstrate that Vitoss Foam Bone Graft Substitute is as safe and as effective as the predicate devices.

Substantial Equivalence:

Information within this submission supports substantial equivalence.

510(k) Summary
Vitoss Bone Graft Substitute Filled Canister

510(k) Number (if known): **K083033**

Sponsor:	Orthovita, Inc. 45 Great Valley Parkway Malvern, PA 19355 USA (t) 610-640-1775 – (f) 610-640-1714
Company Representative:	Deborah L. Jackson, RAC Regulatory Affairs Specialist (email) djackson@orthovita.com
Date Prepared:	November 4, 2008
Device Trade Name:	Vitoss Bone Graft Substitute Filled Canister
Common or Usual Name:	Bone Void Filler
Regulation Number:	888.3045
Regulation Name:	Resorbable calcium salt bone void filler device
Regulatory Class:	Class II
Product Code:	MQV
Predicate Devices:	Vitoss Filled Cartridge – K032130
Device Description:	Vitoss Bone Graft Substitute Filled Canister is a device that combines two Orthovita products, Vitoss Bone Graft Substitute and the Imbibe II Syringe into a kit configuration. The convenience kit provides the Imbibe II Syringe loaded (filled) with Vitoss Bone Graft Substitute and an empty 30cc secondary syringe (Merit Piston Syringe). An adapter valve, which can be connected to the vacuum line in the surgical suite, is also provided. The surgeon can use either the secondary syringe or the vacuum line adapter to aspirate blood or marrow into the Vitoss Filled Canister.

Intended Use:

Vitoss Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Bone Graft Substitute is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Vitoss Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis and spine, which includes posterolateral fusion procedures), and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Vitoss Bone Graft Substitute Filled Canister is intended for use as a piston syringe system for the aspiration of autogenous blood and/or bone marrow. The Canister provides the surgeon with a convenient way to mix autologous blood or bone marrow with Vitoss Bone Graft Substitute and deliver the material to the orthopaedic surgical site.

Performance Data:

Previous testing (e.g., pre-clinical animal, biocompatibility, and in-vitro) have demonstrated that Vitoss Bone Graft Substitute is safe and effective for its intended use.

Substantial Equivalence:

Information within this submission supports substantial equivalence.

510(k) Summary
Vitoss Bone Graft Substitute

510(k) Number (if known): **K083033**

Sponsor:	Orthovita, Inc. 45 Great Valley Parkway Malvern, PA 19355 USA (t) 610-640-1775 – (f) 610-640-1714
Company Representative:	Deborah L. Jackson, RAC Regulatory Affairs Specialist (email) djackson@orthovita.com
Date Prepared:	November 4, 2008
Device Trade Name:	Vitoss Bone Graft Substitute
Common or Usual Name:	Bone Void Filler
Regulation Number:	888.3045
Regulation Name:	Resorbable calcium salt bone void filler device
Regulatory Class:	Class II
Product Code:	MQV
Predicate Devices:	Vitoss Scaffold Synthetic Cancellous Bone Void Filler – K032409 and K994337
Device Description:	Vitoss Bone Graft Substitute is a porous calcium phosphate resorbable bone void filler for the repair of bony defects. It is an osteoconductive porous implant with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone. Pore diameters in the scaffold range from 1 μm to 1000 μm (1 mm). The implant is provided sterile in block and morsel forms. Vitoss Bone Graft Substitute guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When Vitoss Bone Graft Substitute is placed in direct contact with viable hose bone, new bone grows in apposition to the calcium phosphate surfaces of the implant. As the implant resorbs, bone and other connective tissues grow into the space previously occupied by the scaffold. Results from animal studies demonstrate that eighty percent of Vitoss Bone Graft Substitute is resorbed within twelve weeks.

Intended Use:

Vitoss Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Bone Graft Substitute is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Vitoss Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis and spine, which includes posterolateral fusion procedures), and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Performance Data:

Previous testing (e.g., pre-clinical animal, biocompatibility, and in-vitro) have demonstrated that Vitoss Bone Graft Substitute is safe and effective for its intended use.

Substantial Equivalence:

Information within this submission supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 2008

Orthovita, Inc.
% Ms. Deborah L. Jackson, RAC
Regulatory Affairs Specialist
45 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K083033
Trade/Device Name: Vitoss Bone Graft Substitute, Vitoss Bone Graft Substitute Filled Canister, Vitoss Foam Bone Graft Substitute, Vitoss Bioactive Foam Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: October 10, 2008
Received: October 10, 2008

Dear Ms. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K083033

Device Name: Vitoss Bone Graft Substitute

Indications for Use:

Vitoss Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Bone Graft Substitute is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Vitoss Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis and spine, which includes posterolateral fusion procedures), and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR Over-The Counter Use (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083033

Indications for Use Statement

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Device Name: Vitoss Bone Graft Substitute Filled Canister

Indications for Use:

Vitoss Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Bone Graft Substitute is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR Over-The Counter Use (21 CFR 807 Subpart C)	

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(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083033

Indications for Use Statement

510(k) Number (if known): **K083033**

Device Name: Vitoss Foam Bone Graft Substitute

Indications for Use:

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510(k) Number K083033

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Mark A. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083033